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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,877	02/08/2002	Robert C. Downs	36-001810US	9765
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QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C. P O BOX 458 ALAMEDA, CA 94501			SINES, BRIAN J	
			ART UNIT	PAPER NUMBER
			1743	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/071,877	Applicant(s) DOWNS ET AL.	
	Examiner Brian J. Sines	Art Unit 1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2/27/2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-71, 113 and 114 is/are pending in the application.
- 4a) Of the above claim(s) 59-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58, 113 and 114 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

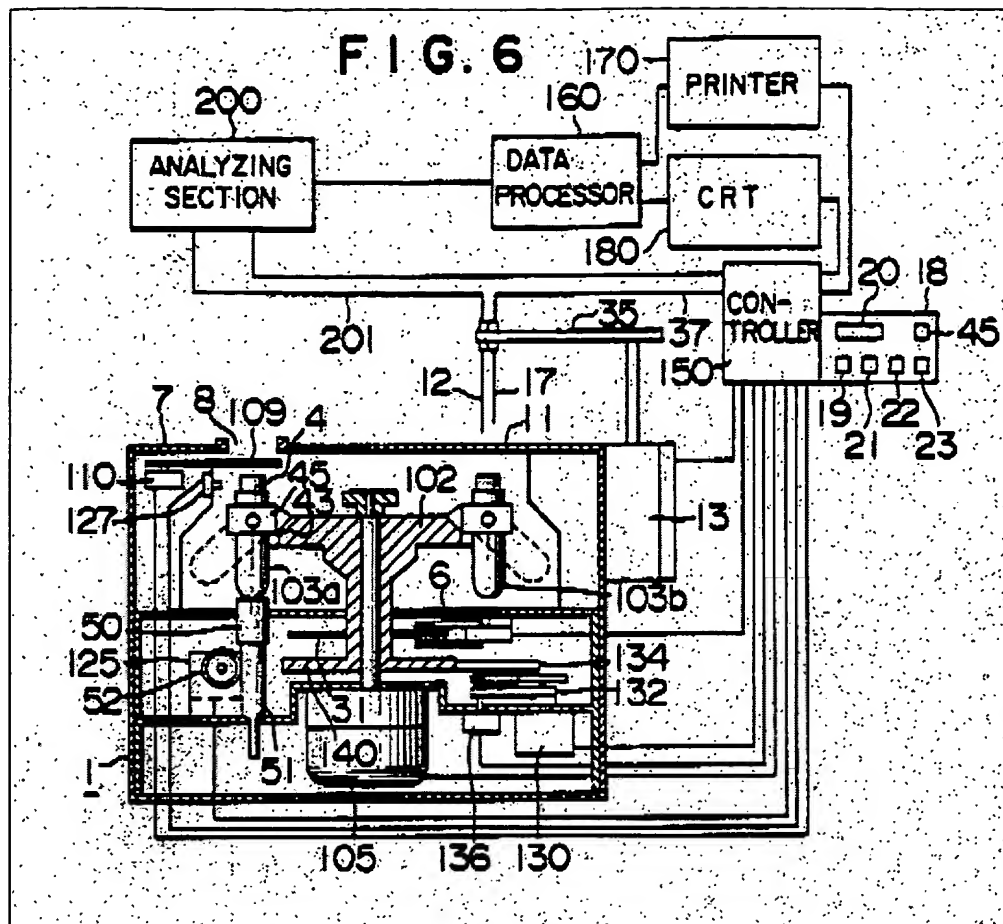
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claims 1 – 9, 14, 16, 19 – 21, 29 – 38, 42 – 49, 53, 54 and 56 – 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida et al. (U.S. Pat. No. 4,708,940) (hereinafter “Yoshida”) in view of Jovanovich et al. (U.S. Pat. No. 6,423,536 B1) (hereinafter “Jovanovich”).

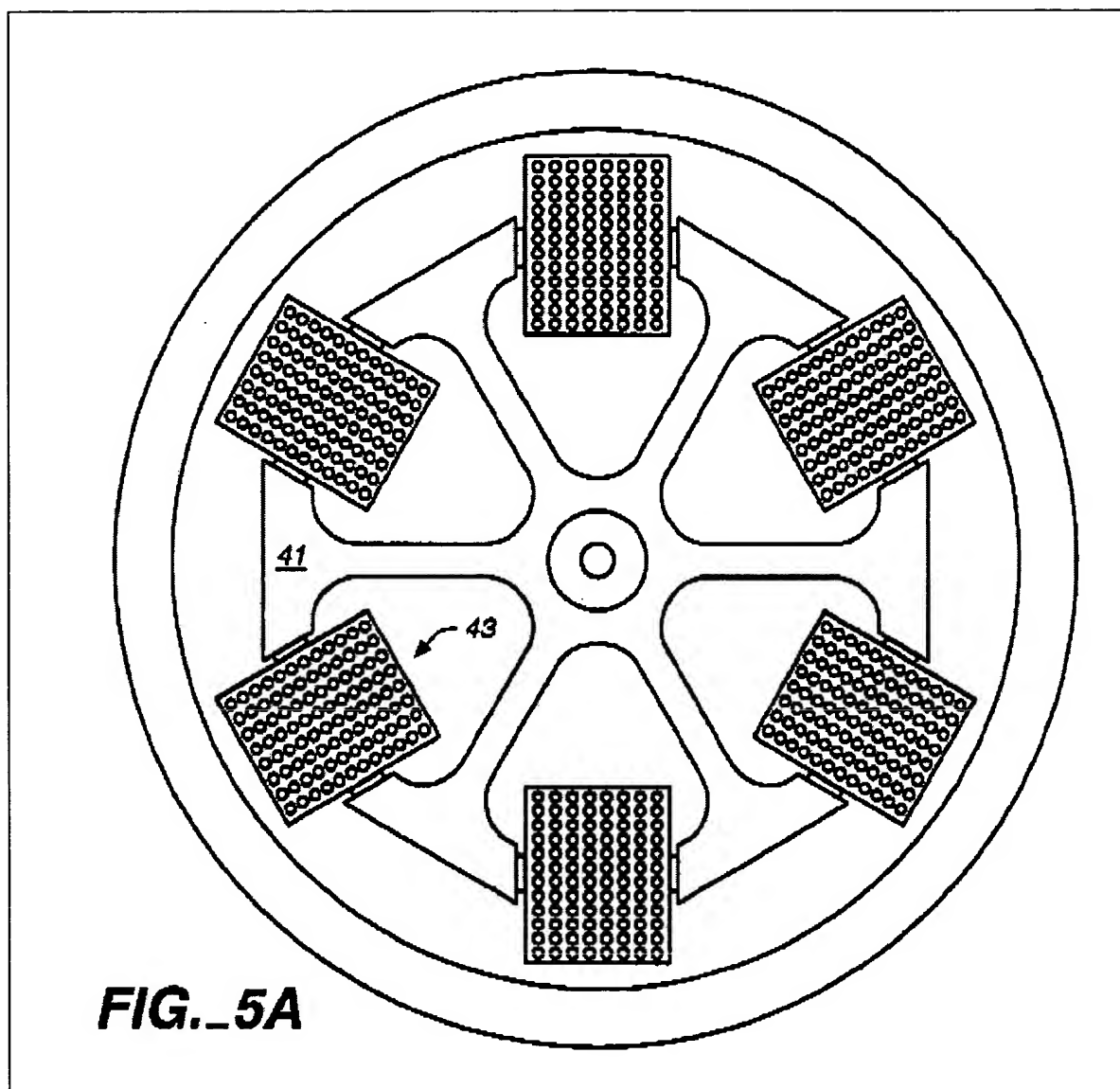
Regarding claims 1, 9, 14, 16, 19, 20, 21, 32, 44, 48 & 58, Yoshida teaches an apparatus comprising: centrifuge rotor (102) comprising a plurality of sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); and a transport mechanism (e.g., driving device 13 & arm 35) configured to move a processing component(s) (e.g., sample take-out pipe 12 & sensing electrode 17) proximal or within the plurality of sample receiving regions (see col. 2, line 28 – col. 7, line 63; figure 6).

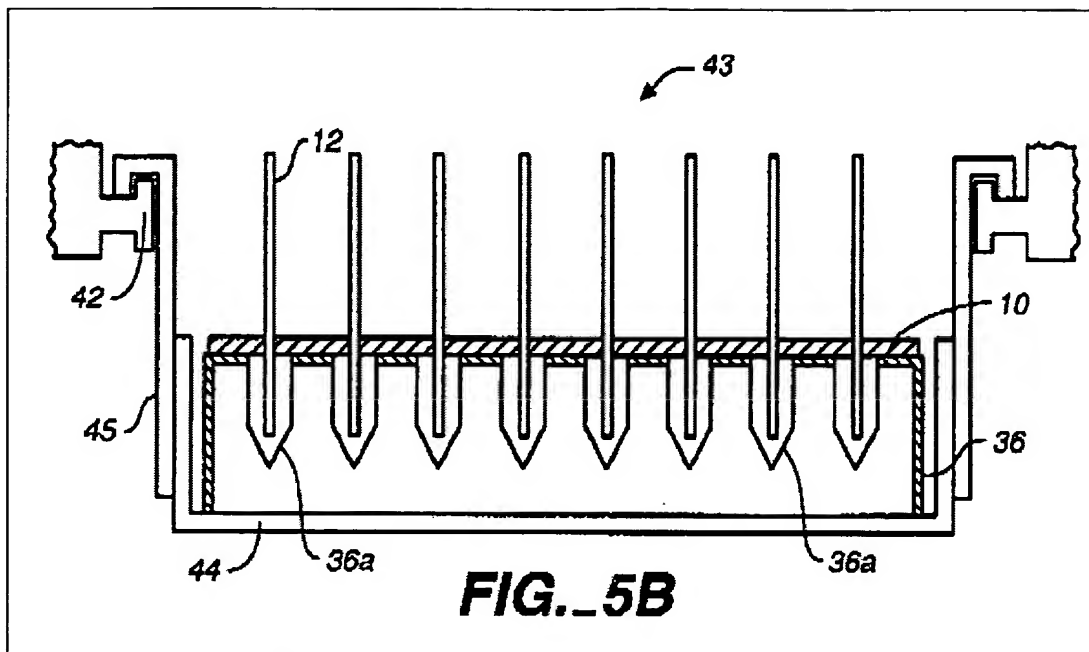


Yoshida does not specifically teach the incorporation of a transport mechanism that is configured to move on or more processing components proximal to or within each of two or more sample receiving regions at substantially the same time, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present in the rotor.

Jovanovich does teach an automated centrifuge system comprising: a microplate bucket (43); centrifuge (42); and a transport mechanism (e.g., automated robot 102 comprising transfer head 104 containing capillary cassette 15) that is configured to move one or more processing components (capillary tubes 12) proximal to or within each of two or more sample vessels

(wells 36a of multiwell plate 36) at substantially the same time, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present in the rotor (41) (see figures 1, 5A and 5B; col. 9, line 56 – col. 11, line 17).

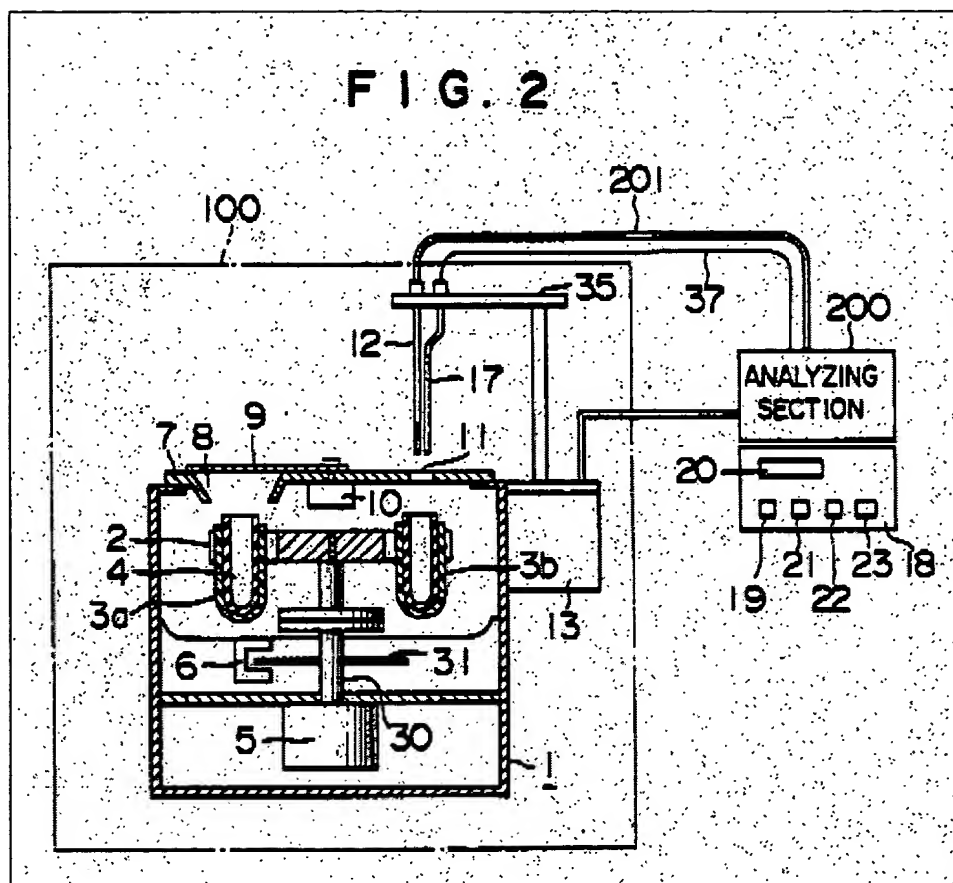


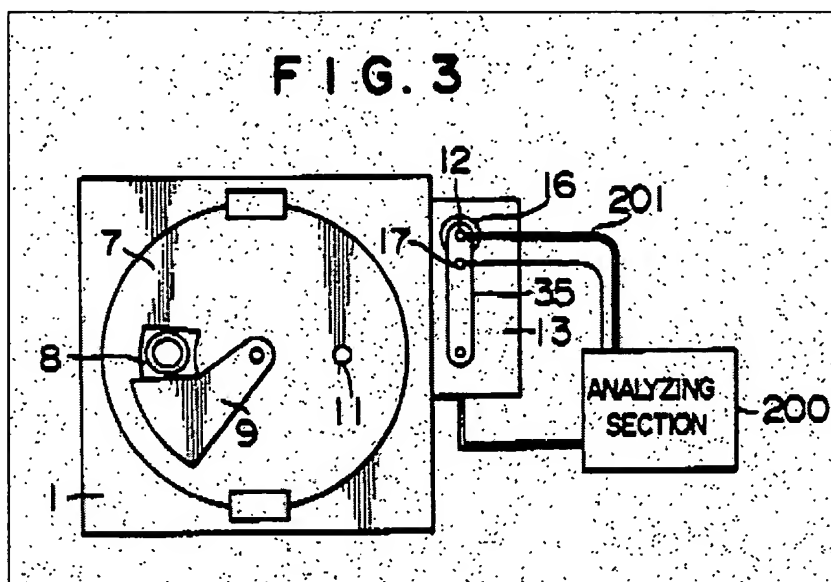


Hence, as evidenced by Jovanovich, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in using a robotic transport mechanism for moving one or more processing components, i.e., sample fluid transfer tubes, proximal to or within two or more sample vessels at the same time and when the sample vessels are present within the rotor. The Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the transport mechanism as claimed with the disclosed centrifuge device to facilitate effective sample processing.

Regarding claims 2 & 3, Yoshida teaches the incorporation of an optical rotor position sensor (e.g., photocoupler 6) (see col. 3, lines 29 – 59).

1. The first group of variables is the "demographic" group, which includes age, sex, and education. These variables are used to control for differences in the population that might affect the results. For example, older individuals might have different preferences for health care than younger individuals, and individuals with higher education might have different health care needs than those with lower education.





Regarding claims 5 & 35, Yoshida teaches the incorporation of a reference index (e.g., disk 31 & pot detector 127), which facilitates rotor positioning (see col. 3, lines 29 – 48; figures 2 & 6).

Regarding claims 6 – 8, Yoshida teaches the incorporation of a motor (driving device 5) (see col. 3, lines 29 – 48).

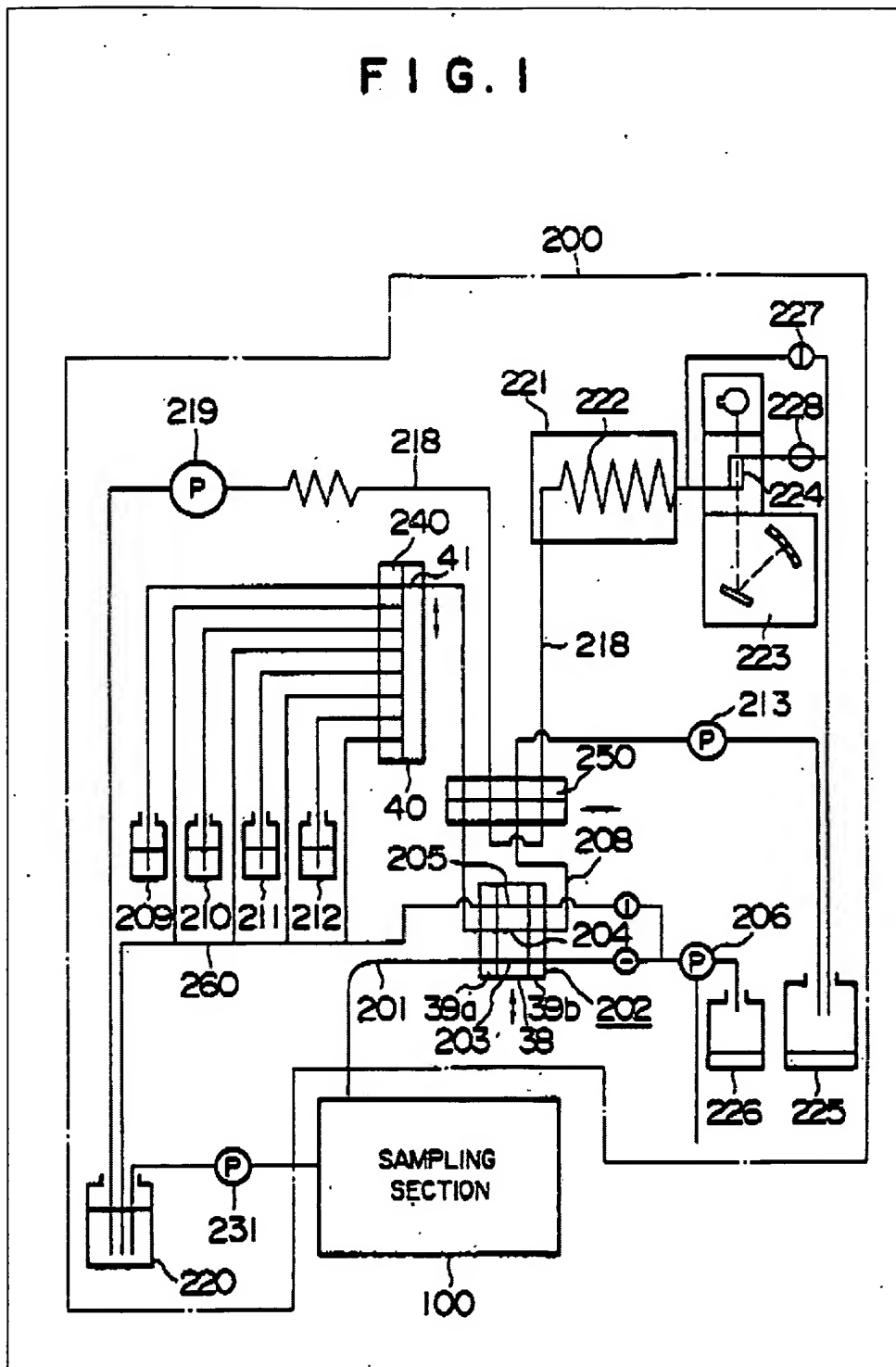
Regarding claims 29 – 31, 33, 34, 36 – 38, 42 & 43, Yoshida teaches the incorporation of a controller (150) comprising a microcomputer for operating the disclosed apparatus (see col. 7, lines 9 – 16). It would have been obvious to a person of ordinary skill in the art to provide appropriate software for monitoring and controlling the automated centrifuge system.

Regarding claims 49, 53 & 54, Yoshida teaches the incorporation of an analyzing section (200) comprising a specimen collector (e.g, flow cell 224), which collects a specimen for analysis (see col. 5, line 35 – col. 63; figure 1).

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Regarding claim 55, it would have been obvious to a person of ordinary skill in the art to incorporate fraction dispensing element, such as tubing positioned within a test tube, for the specimen collection. The use of tubing is well known in the art to facilitate sample fluid transfer.

FIG. 1



Regarding claim 46, Yoshida teaches the incorporation of a rinsing or washing means (e.g., washing tube 16) (see col. 4, lines 5 – 17; figure 3).

Regarding claim 47, Yoshida teaches the incorporation of a rinsing or washing means (e.g., washing tube 16) (see col. 4, lines 5 – 17; figure 3). Yoshida does not indicate the incorporation of two bins, tubes or containers and a runoff ramp. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Therefore, it would have been obvious to incorporate two containers for rinsing. The use of ramps for directing fluid flow are well known in the art (see MPEP 2144.03). Therefore, it would have been obvious to incorporate a runoff ramp with the disclosed apparatus for facilitating runoff fluid flow.

Regarding claim 56, the incorporation of second transport mechanism with the disclosed apparatus would have been obvious to a person of ordinary skill in the art. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04).

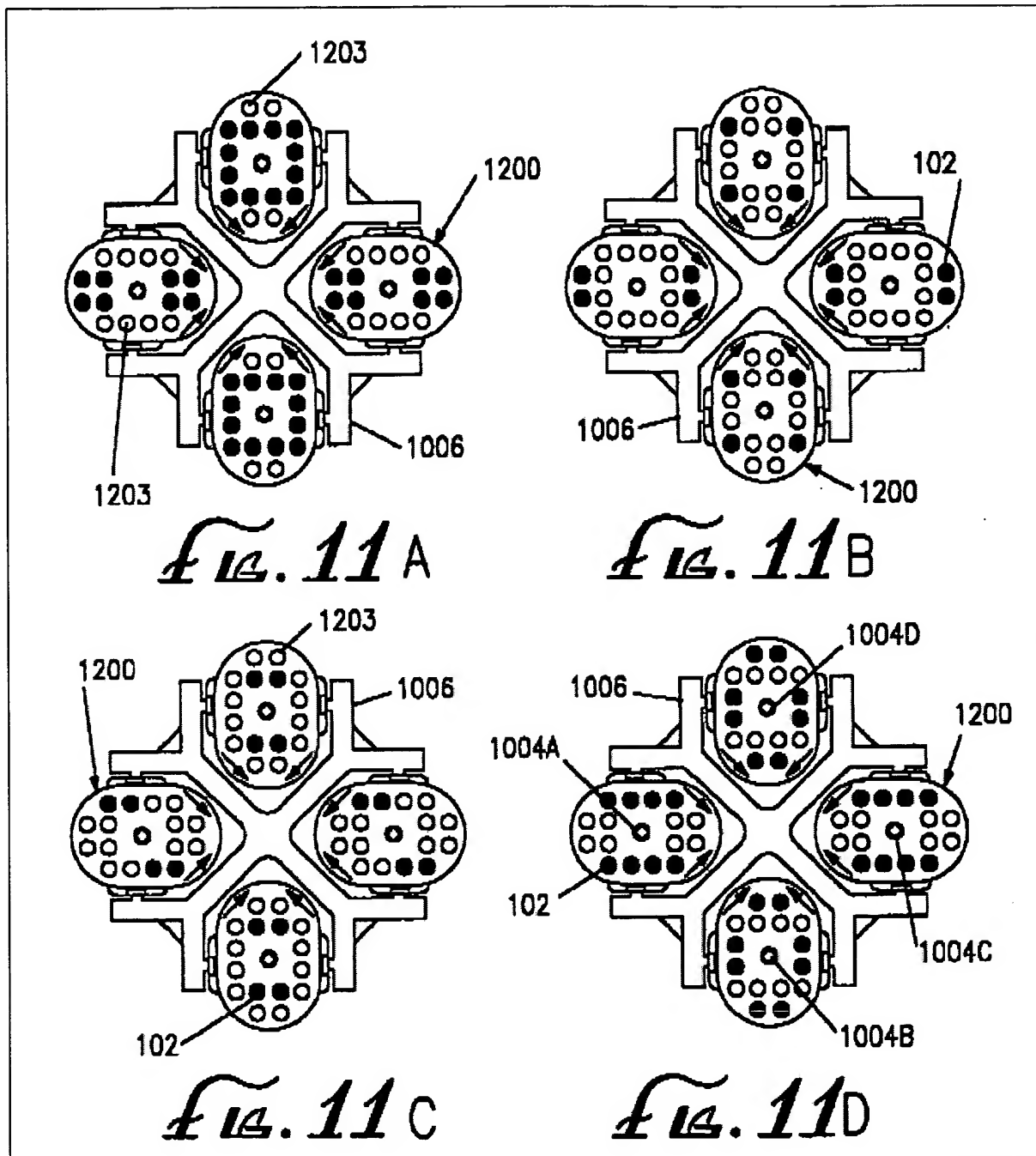
Regarding claim 57, Yoshida teaches an apparatus comprising: sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); various sample processing components (e.g., sample take-out pipe 12 & sensing electrode 17); various hoses (e.g., sample transfer pipe 201), which inherently have tips or ends; various pumps (206, 213, 219 & 231); a fluid source (e.g., reagent reservoirs 209 – 212); a specimen collector (e.g., flow cell 224); various switches or valves (e.g., switching valves 240, 250, movable valve 40, slide valve 202); a waste dump (e.g., washing tube 16) (see col. 3, line 1 - col. 7, line 64; figures 1 – 3, 6 & 7). The Court has recognized that an artisan is presumed to have skill, rather than lack of skill. See *In re Sovish*,

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226 USPQ 771 (Fed. Cir. 1985). It would have been obvious to a person of ordinary skill in the art to provide appropriate tubing or hose connections, pump connections, etc., between the various system components as claimed to facilitate effective device operation.

2. Claims 10 – 13, 15, 17, 18, 23 and 25 – 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida and Jovanovich in view of Pang et al. (U.S Pat. No. 6,060,022 A) (hereinafter “Pang”).

Regarding claims 10 – 13, 15, 17, 18, 23 and 26 – 28, Yoshida does not specifically teach the incorporation of a sample cluster configuration. As evidenced by Pang, the use of a clustered sample holding configuration in addition to a robotic mechanism with automated centrifuge systems is well known in the art (see col. 20, line 59 – col. 21, line 3; figures 11A – 11D). Pang teaches that each cluster or bucket 1200 holds a plurality of containers 12 or test tubes 102 (see col. 11, lines 25 – 54). Hence, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of incorporating such a clustered configuration including a robotic transport mechanism with an automated centrifuge system (see MPEP § 2143.02). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a clustered configuration with an automated centrifuge system.



Regarding claim 25, Pang further teaches the use of a gripper mechanism (2040 & gripper members 2048) that can grasp an inside surface of a sample vessel (e.g., holder 14, sector 300, or test tube rack 600 comprising vessels or containers 12) to facilitate sample vessel transport and insertion. The shaped gripper members (2048) are insertable through a respective

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top wall slot (322) of the sector (300) that contacts the inside surface of sector (322) (see col. 15, lines 43 – col. 16, line 23; figures 14B; 15A – g). Thus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in utilizing a gripping mechanism that is configured to contact and grip an interior surface of a sample holder or sample vessel. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a gripper mechanism that functions by contacting and gripping an inside surface of a sample vessel to facilitate sample vessel transport and processing.

Regarding claim 45, the incorporation of a second rotor as claimed would have been obvious to a person of ordinary skill in the art. The Courts have held that the mere duplication of parts, without any new or unexpected results, is within the ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04).

3. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida and Jovanovich in view of Alam et al. (U.S. Pat. No. 5,792,050 A) (hereinafter “Alam”).

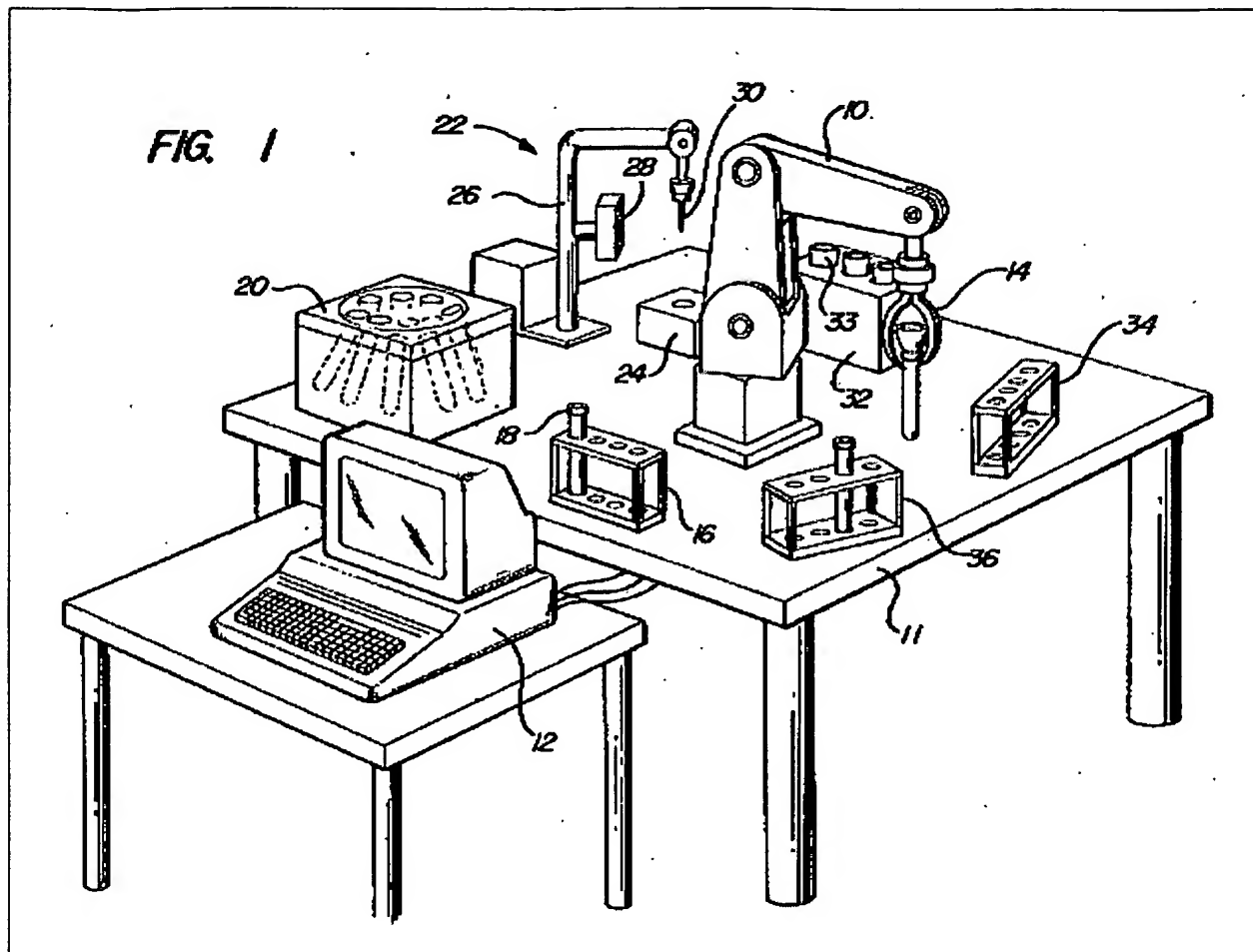
Regarding claim 22, Yoshida does not specifically teach the incorporation of a sonication apparatus. Although Yoshida does teach the incorporation of a fluid transfer tube (e.g., sample transfer pipe 201 & sample take-out pipe 12) (see col. 3, line 29 – col. 6, line 57; figures 2 & 3). Yoshida does teach that the disclosed apparatus is utilized in analyzing blood samples (see col. 1, lines 1 – 16). As evidenced by Alam, the use of sonication probes in assisting in the biochemical analysis of blood samples is well known in the art (see col. 6, lines 55 – 65). Thus, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success of utilizing a sonication device in facilitating the analysis of blood samples. In addition, the Courts have held that the mere duplication of parts, without any new or unexpected results, is within the

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ambit of one of ordinary skill in the art. See *In re Harza*, 124 USPQ 378 (CCPA 1960) (see MPEP § 2144.04). Furthermore, the Courts have held that to provide a mechanical or automatic means to replace manual activity, which accomplishes the same result, is within the ambit of a person of ordinary skill in the art. See *In re Venner*, 120 USPQ 192 (CCPA 1958). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a plurality of sonication devices and fluid transfer tubes as claimed with the disclosed apparatus.

4. Claims 24 & 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida and Jovanovich in view of Roginski et al. (U.S. Pat. No. 4,927,545) (hereinafter “Roginski”).

Regarding claim 24, Yoshida does not specifically teach the incorporation of a robot comprising a gripper mechanism to grasp an outside surface of a sample vessel. Roginski teaches an apparatus comprising a robotic arm (10) including a gripper (14) for transporting test tubes (18) to and from a centrifuge (20) for facilitating blood sample analysis (see col. 3, line 29 – col. 4, line 65; figure 1).



Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating a robotic arm with an automated blood analysis apparatus. As evidenced by Roginski, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating such a robotic arm mechanism with an automated analytical apparatus comprising a centrifuge. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a robotic arm as claimed with the disclosed apparatus.

Regarding claim 41, Roginski teaches the incorporation of a recognition means (e.g., barcode reader 28, 78 & optical sensor 24) (see col. 1, line 29 - col. 8, line 36). Therefore, it

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would have been obvious to a person of ordinary skill in the art to incorporate a recognition means with the centrifuge system for facilitating effective sample processing.

5. Claims 39 & 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida and Jovanovich in view of Taylor (U.S. Pat. No. 4,822,331) (hereinafter "Taylor").

Regarding claims 39 & 40, Yoshida does not specifically teach the incorporation of operator safety members. As evidenced by Taylor, the incorporation of safety mechanisms with laboratory equipment comprising a centrifuge is well known in the art. Taylor does teach the incorporation of a safety member (e.g., motor 103, clutch 160, stop sleeve 171, relay 154, contact 151, run switch 59 & stop switch 185) with a centrifuge apparatus (see col. 8, line 3 – col. 11, line 20). Thus, as evidenced by Taylor, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a safety mechanism with the centrifuge system. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a safety mechanism as claimed with the disclosed apparatus, in order to provide safe operation.

6. Claims 50 – 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida and Jovanovich in view of Feldman (U.S. Pat. No. 5,445,958 A) (hereinafter "Feldman").

Regarding claims 50 – 52, Yoshida does teach the incorporation of a sample analyzing section (200) (see col. 5, lines 35 – 46). Yoshida does not specifically teach the incorporation of a sample purification apparatus comprising a nickel-chelate resin. Yoshida does teach that the disclosed apparatus is utilized in analyzing blood samples (see col. 1, lines 1 – 16). As evidenced by Feldman, the use of liquid column chromatography utilizing a nickel-chelate resin, such as a chelating sepharose resin comprising immobilized iminodiacetic acid groups, in the separation

and analysis of blood plasma samples is well known in the art (see col. 4, line 29 – col. 8, line 55). In addition, the Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate such a separation component as claimed with the disclosed apparatus.

7. Claim 113 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Roginski.

Regarding claim 113, Yoshida teaches an apparatus comprising: centrifuge rotor (102) comprising a plurality of sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); and a transport mechanism (e.g., driving device 13 & arm 35) configured to move a processing component(s) (e.g., sample take-out pipe 12 & sensing electrode 17) proximal or within the plurality of sample receiving regions, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present within the rotor (see col. 2, line 28 – col. 7, line 63; figure 6).

Yoshida does not specifically teach the incorporation of a robot for inserting a sample vessel into a sample receiving region. Roginski teaches an apparatus comprising a robotic arm (10) including a gripper (14) for transporting test tubes (18) to and from a centrifuge (20) for facilitating blood sample analysis (see col. 3, line 29 – col. 4, line 65; figure 1). As shown in figure 1, the centrifuge (20) comprises a single non-vertical fixed-angle cluster comprising receiving regions for test tubes. The Courts have held that things clearly shown in a reference patent drawing qualify as prior art features, even though they are unexplained by the

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specification. See *In re Marz*, 173 USPQ 25 (CCPA 1972). Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating a robotic arm with an automated centrifuge apparatus. As evidenced by Roginski, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating such a robotic arm mechanism with an automated analytical apparatus comprising a centrifuge. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a robotic arm as claimed with the disclosed apparatus.

8. Claim 114 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yoshida in view of Roginski and Hubert et al. (U.S. Pat. No. 6,589,789 B1) (hereinafter "Hubert").

Regarding claim 114, Yoshida teaches an apparatus comprising: centrifuge rotor (102) comprising a plurality of sample receiving regions (e.g., pot holder 103a) and sample vessels (sample pot 4); and a transport mechanism (e.g., driving device 13 & arm 35) configured to move a processing component(s) (e.g., sample take-out pipe 12 & sensing electrode 17) proximal or within the plurality of sample receiving regions, wherein the sample processing components are configured to be inserted into the sample vessels when the sample vessels are present within the rotor (see col. 2, line 28 – col. 7, line 63; figure 6).

Yoshida does not specifically teach the incorporation of a fixed-angle non-vertical sample holding or receiving region configuration. However, Yoshida does indicate in figures 4 and 6 that the disclosed device is capable of operating with the sample receiving regions and sample vessels in a non-vertical or slanted manner. As evidenced by Roginski for example, the use of non-vertical sample holding configurations are very well known in the art. As shown in figure 1, the centrifuge (20) comprises a single non-vertical fixed-angle cluster comprising

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sample receiving regions for test tubes provided by handling robot (10). The Courts have held that things clearly shown in a reference patent drawing qualify as prior art features, even though they are unexplained by the specification. See *In re Marz*, 173 USPQ 25 (CCPA 1972). In addition, as shown in figure 1, a person of ordinary skill in the art would accordingly have had a reasonable expectation for success in incorporating the use of a robotic arm with a non-vertical sample receiving configuration in a centrifuge system. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate the use of a non-vertical configuration as claimed.

Yoshida does not specifically teach the incorporation of a robot for inserting at least two sample vessels at substantially the same time, wherein the sample receiving regions comprise one non-vertical cluster.

Hubert teaches an automated centrifuge loading device comprising a robot (18) that can move a cluster (14) comprising a plurality of sample vessels or tubes into a centrifuge (16) at the same time. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a robot for inserting at least two sample vessels at substantially the same time, wherein the sample receiving regions comprise one non-vertical cluster.

Response to Arguments

Applicant's arguments with respect to the present claims have been considered, but are moot in view of the new ground(s) of rejection.

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

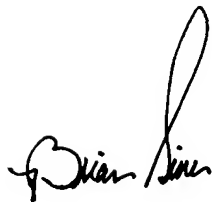
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Brian Lin". The signature is stylized with a large, looping initial "B" and a long, sweeping underline.